

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appellant	:	BRISTER, Mark		
Filed	:	October 24, 2005		
TC/A.U.	:	3731		
Examiner	:	HOUSTON, Elizabeth		
Docket No.	:	P1187US		
Customer No.	:	28390		
Title	:	STENT WITH INTERMITTENT COATING		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

APPEAL BRIEF

Dear Sir:

Please consider Appellant's brief as follows:

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1. REAL PARTY IN INTEREST

The real party in interest is Assignee Medtronic Vascular, Inc., a corporation having an office and a place of business at 3576 Unocal Place, Santa Rosa, California 95403.

2. RELATED APPEALS AND INTERFERENCES

Appellant and the undersigned attorneys are not aware of any appeals, judicial proceedings, or any interferences which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1, 3-6, and 8-25 are pending.

Claims 1, 3-6, and 8-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro, *et al.* (the *Castro* patent) in view of U.S. Patent No. 5,873,904 to Ragheb, *et al.* (the *Ragheb* patent).

Claims 1, 3-6, and 8-25 are the claims on appeal. *See* Claims Appendix.

4. STATUS OF AMENDMENTS

No amendments to the claims were entered subsequent to the final Office Action mailed on November 10, 2010.

5. SUMMARY OF CLAIMED SUBJECT MATTER

In this Summary of Claimed Subject Matter, all citations are to the specification of United States Patent Application 10/531,822 as filed, amended paragraph [0036], and replacement Figure 7. All citations are illustrative only and additional support for the cited element may be found elsewhere in the specification. *See* Figures 1-7; paragraph [0020]-[0039]; specification: page 4, line 14 – page 10, line 23. Specific citations below include both the paragraph number in the published application and the page/line number in the application as filed.

Independent Claim 1:

A stent delivery system comprising:

a *catheter* (Figure 1; element 105; paragraph [0021]; specification: page 4, line 24 – page 5, line 3);

a *balloon* (Figure 1; element 105; paragraph [0021]; specification: page 4, line 24 – page 5, line 3) operably attached to the catheter;

a *stent* (Figure 1-4; element 120, 150; paragraph [0021]-[0024], [0027]-[0031]; specification: page 4, line 24 – page 5, line 25; page 6, line 16 – line 22) disposed on the balloon, the stent having a plurality of end-to-end cylindrical *stent segments* (Figure 1-4; element 121, 122, 123, 124, 160; paragraph [0022], [0023], [0026], [0029]; specification: page 5, line 4 – page 5, line 20; page 6, line 11 – page 6, line 15; page 6, line 30 – page 7, line 10), the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of longitudinally adjacent cylindrical stent segments; and

a coating including a first *coating section* (Figure 1-4; element 126, 128, 130, 132, 134, 136; paragraph [0020], [0023], [0028]-[0032]; specification: page 4, line 14 – page 4,

line 23; page 5, line 19 – page 5, line 20; page 6, line 27 – page 8, line 6) comprising a first polymer and a second *coating section* (Figure 1-4; element 126, 128, 130, 132, 134, 136; paragraph [0020], [0023], [0028]-[0032]; specification: page 4, line 14 – page 4, line 23; page 5, line 19 – page 5, line 20; page 6, line 27 – page 8, line 6) comprising a second polymer, the first polymer being different than the second polymer;

wherein:

the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and

the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and

the first region and the second region are discrete, and the first coating section and the second coating section are discrete.

Independent Claim 6:

A coated stent comprising:

a *stent* (Figure 1-4; element 120, 150; paragraph [0021]-[0024], [0027]-[0031]; specification: page 4, line 24 – page 5, line 25; page 6, line 16 – line 22) having a plurality of end-to-end cylindrical *stent segments* (Figure 1-4; element 121, 122, 123, 124, 160; paragraph [0022], [0023], [0026], [0029]; specification: page 5, line 4 – page 5, line 20; page 6, line 11 – page 6, line 15; page 6, line 30 – page 7, line 10), the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and

a coating including a first *coating section* (Figure 1-4; element 126, 128, 130, 132, 134, 136; paragraph [0020], [0023], [0028]-[0032]; specification: page 4, line 14 – page 4, line 23; page 5, line 19 – page 5, line 20; page 6, line 27 – page 8, line 6) comprising a first polymer and a second *coating section* (Figure 1-4; element 126, 128, 130, 132, 134, 136; paragraph [0020], [0023], [0028]-[0032]; specification: page 4, line 14 – page 4, line 23; page 5, line 19 – page 5, line 20; page 6, line 27 – page 8, line 6) comprising a second polymer, the first polymer being different than the second polymer;

wherein:

the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and

the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and

the first region and the second region are discrete, and the first coating section and the second coating section are discrete.

Independent Claim 11:

A method for producing a coated stent comprising:

providing a stent having a plurality of end-to-end cylindrical stent segments (Figure 6; element 220; paragraph [0034]; specification: page 9, line 5 – page 9, line 11), the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments;

mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (Figure 6; element 222; paragraph [0034]; specification: page 9, line 5 – page 9, line 11);

applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the

longitudinally adjacent cylindrical stent segments (Figure 6; element 224; paragraph [0034]; specification: page 9, line 5 – page 9, line 11);

mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution (Figure 6; element 226; paragraph [0034]; specification: page 9, line 5 – page 9, line 11); and

applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments (Figure 6; element 228; paragraph [0034]; specification: page 9, line 5 – page 9, line 11),

wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state.

Independent Claim 18:

A system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, comprising:

means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (replacement Figure 7; element 245; amended paragraph [0036], paragraph [0037]; specification: page 9, line 19 – page 10, line 9);

means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments (replacement Figure 7; element 242, 244, 246; amended paragraph [0036], paragraph [0037]; specification: page 9, line 19 – page 10, line 9);

means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution (replacement Figure 7; element 245; amended paragraph [0036], paragraph [0037]; specification: page 9, line 19 – page 10, line 9); and

means for applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments (replacement Figure 7; element 242, 244, 246; amended paragraph [0036], paragraph [0037]; specification: page 9, line 19 – page 10, line 9),

wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state.

Independent Claim 22:

A coated stent comprising:

a *stent* (Figure 1-4; element 120, 150; paragraph [0021]-[0024], [0027]-[0031]; specification: page 4, line 24 – page 5, line 25; page 6, line 16 – line 22) having a plurality of end-to-end cylindrical *stent segments* (Figure 1-4; element 121, 122, 123, 124, 160; paragraph [0022], [0023], [0026], [0029]; specification: page 5, line 4 – page 5, line 20; page 6, line 11 – page 6, line 15; page 6, line 30 – page 7, line 10), the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second *region* (Figure 2-4; element 162, 166, 168, 170, 172, 180, 182, 184, 186, 210, 212, 214, 216; paragraph [0029]-[0032]; specification: page 6, line 30 – page 8, line 6) continuous across at least one pair of the longitudinally adjacent cylindrical stent segments;

a first polymer including a first therapeutic agent, the first polymer being directly adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and

a second polymer including a second therapeutic agent, the second polymer being directly adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, the first polymer being different than the second polymer,

wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 3-6, and 8-25 are patentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,616,765 to Castro, *et al.* (the *Castro* patent) in view of U.S. Patent No. 5,873,904 to Ragheb, *et al.* (the *Ragheb* patent).

7. ARGUMENTS

The Appellant respectfully submits that claims 1, 3-6, and 8-25 are allowable over the cited references under 35 U.S.C. §103(a), and that the rejection of claims 1, 3-6, and 8-25 should be reversed.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Appellant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claims 1, 3-6, and 8-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro, et al. (the Castro patent) in view of U.S. Patent No. 5,873,904 to Ragheb, et al. (the Ragheb patent).

The Appellant respectfully asserts that the *Castro* patent and the *Ragheb* patent, alone or in combination, fail to teach or suggest all the claim limitations.

The *Castro* patent and the *Ragheb* patent fail to disclose, teach, or suggest:

a stent delivery system including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the

longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 1; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 6; or

a method for producing a coated stent including providing a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments; mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer

surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 11;

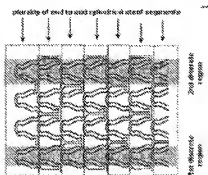
a system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, including: means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and means for applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 18; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; a first polymer including a first therapeutic agent, the first polymer being adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and a second polymer including a second therapeutic agent, the second polymer being adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a

second coating section of the coating, the first polymer being different than the second polymer, wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 22.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. See Abstract. Composition 10 may be applied along struts 68 of prosthesis 12 in a variety of deposition patterns and having a variety of thicknesses. See Figures 7A-15D; column 15, line 34 – column 19, line 18.

On pages 2 and 3 of the Office Action dated November 10, 2010, the Examiner presented one particular pattern as seen below and asserted that the choosing of regions is subjective and not limited by the claims. The Appellant respectfully disagrees.



Assuming *arguendo* the pattern posited would be one which satisfies the Appellant's claims, the pattern is not disclosed in the *Castro* patent. The *Castro* patent discloses a patterned coating on a prosthesis, but fails to disclose the pattern extending over regions as claimed. The regions are limited in the claims so that the discrete first region is continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and the discrete second region is continuous across at least one pair of the longitudinally adjacent cylindrical stent segments. Further, the *Castro* patent fails to disclose discrete coating sections over the regions.

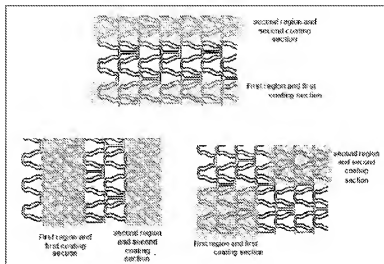
At most, the *Ragheb* patent discloses that the bioactive material may be posited on the one surface of structure 12 in a specific geometric pattern. For example, the tips or arms of a stent may be free of bioactive material, or the bioactive material may be applied in parallel lines,

particularly where two or more bioactive materials are applied to the same surface. See column 19, line 64 - column 20, line 3. This is the sole and complete disclosure of the *Ragheb* patent regarding geometric patterns.

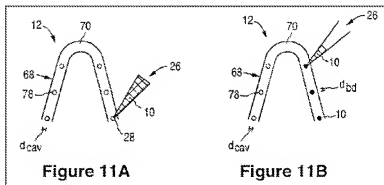
On page 3 of the Office Action dated November 10, 2010, the Examiner asserted that the *Ragheb* patent discloses the concept of applying coatings in different patterns. The Appellant respectfully notes that the disclosure of the *Ragheb* patent regarding geometric patterns is limited to those few features discussed in the previous paragraph and that the combination of the *Castro* patent and the *Ragheb* patent would not suggest the Appellant's invention as claimed to one skilled in the art, i.e., the difference between the claimed invention and the prior art is too great to establish *prima facie* obviousness.

In the Response to Arguments on page 7 of the Office Action dated November 10, 2010, the Examiner noted that one cannot show nonobviousness by attacking references individually. The Appellant respectfully submits that all the claim limitations must be taught or suggested by the prior art for a showing of obviousness: as discussed above, the *Castro* patent and the *Ragheb* patent, alone or in combination, fail to do so. The scope and content of the prior art must be determined in order to examine differences between the prior art and the claims at issue under a *Graham* analysis for obviousness.

On page 2 of the Advisory Action dated February 1, 2011, the Examiner presented three possible scenarios for discrete coating sections over regions of a stent, as shown below. The appellant respectfully asserts that such coating regions are completely the product of the Examiner and are not taught or suggested by the *Castro* patent as required to establish *prima facie* obviousness.



In fact, the *Castro* patent only discloses minute patterns on the individual stent wires and fails to disclose macroscopic patterns across stent segments over the stent as claimed. This is clearly shown by the examples of Figure 7A through Figure 15 D. Figures 11A and 11B are presented below as examples. A nozzle 26 containing composition 10 is used to deposit the composition 10 into cavities 78 of a single strut 68 of prosthesis 12. See Figure 11 A, 11 B; column 16, line 35-57.



The *Ragheb* patent also fails to disclose macroscopic patterns across stent segments over the stent as claimed.

On page 2 of the Advisory Action dated February 1, 2011, the Examiner further asserted that the *Ragheb* patent discloses applying different active agents to different sections of the stent. The Appellant respectfully disagrees. At most, the *Ragheb* patent discloses that different

bioactive agents may be applied to different sections or surfaces of the device (*see* column 19, line 19-21), and further discloses that bioactive material may be posited on the one surface of structure 12 in a specific geometric pattern, that tips or arms of a stent may be free of bioactive material, and that the bioactive material may be applied in parallel lines, particularly where two or more bioactive materials are applied to the same surface (*see* column 19, line 64 – column 20, line 3). Without regard to the method of application, however, what is important is that the bioactive material need only be physically held in place until the porous layer 20 is deposited over it. This can avoid the use of carriers, surfactants, chemical binding and other such methods often employed to hold a bioactive agent on other devices. The additives used in such methods may be toxic, or the additives or methods may alter or degrade the bioactive agent, rendering it less effective, or even toxic itself. *See* column 19, line 32-41. The coating section as claimed is a polymer or a polymer plus a therapeutic agent, thus the *Ragheb* patent teaches away from the Appellant's invention as claimed.

Claims 3-5; claims 8-10; claims 12-17; claims 19-21; and claims 23-25 depend directly or indirectly from independent claims 1, 6, 11, 18, and 22, respectively, and so include all the elements and limitations of their respective independent claims. The Appellant therefore submits that the dependent claims are allowable over the *Castro* patent and the *Ragheb* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 1, 3-6, and 8-25 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent and the *Ragheb* patent is respectfully requested.

8. SUMMARY

The Appellant respectfully submits that claims 1, 3-6, and 8-25 fully satisfy the requirements of 35 U.S.C. §103. In view of the foregoing, reversal of the rejection of claims 1, 3-6, and 8-25 is respectfully requested.

Respectfully submitted,

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9. CLAIMS APPENDIX

Claim 1 (previously presented): A stent delivery system comprising:

a catheter;

a balloon operably attached to the catheter;

a stent disposed on the balloon, the stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments; and

a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer;

wherein:

the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and

the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and

the first region and the second region are discrete, and the first coating section and the second coating section are discrete.

Claim 2 (cancelled):

Claim 3 (original): The stent delivery system of claim 1 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent.

Claim 4 (original): The stent delivery system of claim 1 wherein the first coating section includes a therapeutic agent.

Claim 5 (previously presented): The stent delivery system of claim 1 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, and spotted patterns.

Claim 6 (previously presented): A coated stent comprising:

a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and

a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer;

wherein:

the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and

the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and

the first region and the second region are discrete, and the first coating section and the second coating section are discrete.

Claim 7 (cancelled):

Claim 8 (previously presented): The coated stent of claim 6 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent.

Claim 9 (original): The coated stent of claim 6 wherein the first coating section includes a therapeutic agent.

Claim 10 (previously presented): The coated stent of claim 6 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and spotted patterns.

Claim 11 (previously presented): A method for producing a coated stent comprising:

providing a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments;

mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments;

mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments,

wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state.

Claim 12 (original): The method of claim 11 wherein applying the first polymer solution and applying the second polymer solution further comprises applying the first polymer solution and applying the second polymer solution simultaneously.

Claim 13 (original): The method of claim 11 further comprising curing the first polymer solution and curing the second polymer solution.

Claim 14 (original): The method of claim 11 wherein applying the first polymer solution to the first region further comprises:

mounting the stent in a coating fixture; and
spraying the first polymer solution on the first region.

Claim 15 (original): The method of claim 14 wherein the coating fixture is a computerized numerically controlled machine.

Claim 16 (original): The method of claim 14 wherein spraying the first polymer solution on the first region further comprises spraying the first polymer solution by a spraying method selected from the group consisting of micro-spraying and inkjet spraying.

Claim 17 (original): The method of claim 11 wherein applying the first polymer solution to the first region further comprises applying the first polymer solution by an application method selected from the group consisting of pad printing, inkjet printing, rolling, painting,

spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

Claim 18 (previously presented): A system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, comprising:

means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments;

means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

means for applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments,

wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state.

Claim 19 (original): The system of claim 18 wherein means for applying the first polymer solution and means for applying the second polymer solution further comprises means for applying the first polymer solution and the second polymer solution simultaneously.

Claim 20 (original): The system of claim 18 further comprising means for curing the first polymer solution and means for curing the second polymer solution.

Claim 21 (original): The system of claim 18 wherein means for applying the first polymer solution to the first region further comprises:

means for mounting the stent in a coating fixture; and

means for spraying the first polymer solution on the first region.

Claim 22 (previously presented): A coated stent comprising:

a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments;

a first polymer including a first therapeutic agent, the first polymer being directly adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and

a second polymer including a second therapeutic agent, the second polymer being directly adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, the first polymer being different than the second polymer,

wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state.

Claim 23 (previously presented): The coated stent of claim 22 wherein the discrete first region and the discrete second region are separated by a bare section on the outer surface of the stent.

Claim 24 (original): The coated stent of claim 23 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 1 millimeter (0.03937 inches)

Claim 25 (original): The coated stent of claim 24 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 0.025 millimeter (0.00098 inches).

Claims 26-27 (cancelled)

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.